

REMARKS

Claims 1-4, 6-9, 26-27, 31-33 and 42-47 are pending in the application.

Claims 6-9, 27 and 31-33 have been withdrawn by the Examiner.

Claim 41 has been canceled.

Claims 1, 7-8 and 27 have been amended to further define Applicant's methods. Support for the amendments is in Claim 41 (BMI), originally filed Claim 22-23, and paragraphs [0024], [0045], [0046] and [0051] (estimate of body weight with/without odorants) of the published application US 2004/0137086.

The claims have been amended to merely clarify language used in the claims and/or the subject matter claimed. The scope of the claims is intended to be the same after the amendment as it was before the amendment. No new matter has been added with the amendments to the claims or the addition of the new claims.

Rejection of Claims under 35 U.S.C. § 112(1).

At pages 2-15, the Examiner rejected Claims 1-4, 26 and 41-47 under Section 112(1) for lack of enablement. This rejection is respectfully traversed.

The Examiner maintains that the experimental example in the Test Study does not provide support for Applicant's methods as claimed.

As stated by the U.S. Court of Customs and Patent Appeals in *In re Borkowski*, 422 F.2d 904, 910, 164 USPQ 642, 646 (CCPA 1970), "there is no magical relation between the number of representative examples and the breadth of the claims; the number and variety of examples are irrelevant if the disclosure is 'enabling' and sets forth the 'best mode contemplated.'" As further stated by the CCPA, "[t]he sufficiency of the disclosure depends not on the number but rather on the nature of the claimed compounds per se and the nature of the supporting disclosures." *In re Cavallito*, 282 F.2d 363, 367, 127 USPQ 206, 207 (CCPA 1960).

According to Section 112, an Applicant is required to teach how to use an invention, and it is well settled that it is not necessary that the specification disclose every operative example when one skilled in the art is fully apprised by the disclosure of what the invention is and how to use it. A disclosure that contains representative examples which provide reasonable assurance to one skilled in the art that the compounds falling within the scope of the claim will possess the described utility is all that is required.

Applicant has fully described the methods as claimed in the specification and further provided an Example (Test Study) to demonstrate administration of odorant compositions to an individual to alter their perception of the body weight of another person – as defined in the claims.

Satisfaction of the enablement requirement of Section 112 is not precluded by the necessity for some experimentation, such as routine screening. The key word is "undue" not "experimentation." *In re Angstadt and Griffin*, 190 USPQ 214, 219 (CCPA 1976). A considerable amount of experimentation is permissible if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Jackson*, 217 USPQ 804 (Bd. App. 1982).

Steps in administering an odorant composition are described and defined. As recited in the claims, a hedonically positive odorant composition (mixture of floral and spice odorants) is administered to a first person by inhalation in an effective amount such that an estimate by the first person of the body weight of a second person (BMI of about 25 or greater) is about 5-10% less than actual body weight of the second person and less than an estimate of the body weight of the second person by the first person before inhalation of the composition (i.e., without the odorants).

Identification of odorant compositions. The claims are limited to mixtures of certain floral and spice odorants that are hedonically positive and alter the inhaling individual's perception of body weight – and thus do not call for just any odorant or odorant mixture. The characteristics of the odorants in the mixtures recited in the claims are well understood in the odorant arts, and one skilled in the odorant arts would readily ascertain and provide suitable odorant mixtures from various sources that have the recited floral or spice odorant character that would achieve the desired effect when inhaled by a first person to modify the first person's perception of the body weight of a second person according to Applicant's invention as claimed.

Applicant has described sources of commercial odorants, which are exemplary, that are within the scope of the claims. See at paragraph [0022] of Applicant's published application US 2004/0137086. One of ordinary skill in the odorant arts would be able to readily ascertain sources of the recited odorants and whether a substance had a floral aroma (e.g., jasmine, lilac, etc.) or spice aroma (e.g., cinnamon, ginger, oriental spice, etc.).

Known methods in the art can be readily used for identifying and/or preparing odorants within the scope of the claims – as evidenced by USP 5,031,764 (Meador) and USP 6,606,566 (Sunshine), as previously discussed.

From the commercial sources and the other information provided by Applicant, one skilled in the odorant arts would readily identify and formulate mixtures of suitable odorants that have the characteristics of the recited odorants to achieve the desired effect.

Appellant has also described methods that can be used to **screen odorants** for effectiveness. As described at paragraphs [0023] and [0025] of Applicant's published application US 2004/0137086, *and further presented in the Example (Test Study) at paragraph [0045]*, screening an odorant and odorant mixture for positive hedonics can be conducted by administering the odorant/mixture to an individual who is questioned as to a positive or negative reaction to the pleasantness of the scent (i.e., to identify the composition as hedonically positive or hedonically negative).

As described at paragraph [0024], screening an odorant and odorant mixture for effectiveness in modifying perception of body weight of another individual can be conducted by administering the odorant/mixture to an individual for inhalation, having the individual estimate the body weight of a person, comparing the estimate of the body weight to actual body weight of the person to provide a "difference value", comparing the difference value to a "control value" to determine the statistical significance of the difference value, and eliminating the odorant or odorant mixture as being ineffective for altering perception of body weight if not statistically significant. The control value can be derived by having the person estimate the body weight of the individual without inhaling the composition (or inhaling an odorless control composition), and comparing the body weight estimate with the actual weight of the individual to provide the control value, preferably before administering the test composition to be screened.

Based on Applicant's disclosure and the knowledge in the art, one skilled in the art would clearly be able to identify hedonically positive odorant mixtures for use in Applicant's methods.

Administration of Odorant Compositions to Alter Perception of Body Weight. Steps in the administration of the odorant mixtures are described throughout the specification and in the Example (Test Study). See for example, at paragraphs [0016] and [0018] of the published application US 2004/0137086.

[0016] According to the method, an odorant or odorant mixture is administered to a subject for sniffing and inhalation into the nasal passageway, to deliver an amount of the odorant or odorant mixture effective to alter the subject's perception of weight. ...Preferably, the odorant or odorant mixture that is administered is an aromatic substance to which the inhaling individual displays a positive hedonic response.

...
[0018] In a preferred embodiment, the subject individual is presented with a suprathreshold concentration (e.g., about 25-55 decismel units) of the odorant or odorant mixture that is not so high as to become an irritant (trigeminal), and generally inhales the odorant for about three seconds to about one minute, preferably about 20 seconds. Preferably, the level or concentration of the odorant or odorant mixture and/or mode of administering the composition is sufficient to overcome competing or conflicting ambient odors that may act to nullify its effect.

Dispensing the odorant composition is described, for example, at paragraphs [0027] and at [0031] and [0032].

[0027] In one embodiment, the method of the invention can be used to alter the perception of a second person (observer) of the body weight of an overweight individual, particularly an obese or morbidly obese individual, and thus increase the attractiveness and positive perception of the overweight/obese person to the observer. ...*In one embodiment of the method, an effective concentration of the odorant or odorant mixture is administered directly to the observing individual for inhalation*, for example, by means of the odorant or odorant mixture applied to their body (e.g., skin) or clothing, or through the use of a dispensing device containing the odorant or odorant mixture (e.g., spray container, blister pack, cloth, etc.) which is presented to the observing individual. *In another embodiment of the method, the odorant or odorant mixture is applied to the overweight individual* such that a sufficient concentration of the odorant or odorant mixture can be inhaled by the observing individual to effect a change in their perception of the body weight of the overweight individual.

...
[0031] The odorant or odorant mixture is dispensed to the person in a form that provides a vaporous emission for inhalation. The odorant or odorant mixture can be administered to an individual, for example, by applying the odorant/odorant mixture to the individual's skin in a number of forms including, for example, as a liquid, powder, gel, cream, paste, and the like. The odorant or odorant mixture can be administered in combination with an odorless carrier such as mineral oil or water and/or odorless additives, and can be formulated with a viscosity effective to allow for aerosolization. The odorant composition can be dispensed onto the skin, for example, by direct application, by contact with a cloth carrying the composition, by an aerosol or nonaerosol spray, among other modes of application.

[0032] The odorant or odorant mixture can also be inhaled from a device, for example, from a capped vessel containing a liquid or solid form of the odorant or mixture, the liquid form being optionally absorbed to a wicking material, from a blister pack or scratch-and-sniff odor patch containing microcapsules of the odorant, as a spray from an aerosol or non-aerosol pump-type spray device, as a nasal spray, by means of a scented cloth, and the like. It is preferred that the odorant or odorant mixture is provided in a portable dispenser that is easily transportable and readily accessible.

Likewise, the Example describes an embodiment of administering the odorant composition to the test subjects by application to the Test Model. See at paragraph [0045] (emphasis added).

[0045] ...For each day of the study, the odorants 1-3 were sequentially applied over separate days (i.e., one odorant per day for three consecutive days) to the model at non-irritant, suprathreshold levels. The testing was conducted indoors. The model stood at a distance that *was predetermined to be adequate for normosmics to be able to detect the applied odorant at a non-irritant, suprathreshold level.*

The Effect of the Odorant Mixtures. The specification, for example, at paragraphs [0024] (screening) and [0026], also describes how the effect and effectiveness of the odorant compositions recited in the claims can be assessed according to the estimate of body weight by the first individual upon inhalation of the composition (emphasis added).

[0024] For example, a method of screening an odorant or a mixture of odorants for effectively altering perception of body weight can comprise the steps of: administering a suprathreshold and non-irritant concentration of a composition consisting essentially of one or more odorants to an individual for inhalation; *having the individual estimate the body weight of a person; comparing the estimate of the body weight to actual body weight of the person to provide a "difference value"; comparing the difference value to a "control value" to determine the statistical significance of the difference value; and eliminating the odorant or odorant mixture as being ineffective for altering perception of body weight if not statistically significant. The control value can be derived by having the person estimate the body weight of the individual without inhaling the composition (or inhaling an odorless control composition), and comparing the body weight estimate with the actual weight of the individual to provide the control value, preferably before administering the test composition to be screened.*

...
[0026] ...to effectively change the individual's perception of another individual's body weight. *Such an effect can be assessed and measured subjectively by interviewing and questioning the individual about their perception of body weight before and after the administration of the odorant or odorant mixture, and assessing their response.*

The Example (Test Study) also describes having the test subjects estimate the test model's weight with and without inhalation of the odorant mixtures to determine the effect and effectiveness of the odorant compositions. See at paragraphs [0045] to [0046] (emphasis added).

[0045] ...For each day of the study, the odorants 1-3 were sequentially applied over separate days (i.e., one odorant per day for three consecutive days) to the model at non-irritant, suprathreshold levels. ...The subjects were asked by one of the investigators to estimate the model's weight. ...

[0046] Subjects were then queried on their detection and hedonics of each of the Odorants 1-3. *On each day, estimates were performed by subjects without any odorant applied to the woman model in the control trials and with an Odorant 1-3 applied to the model in the experimental trials. Results were statistically analyzed independently for significance (p<0.05) by the*

University of Illinois School of Public Health. *Comparisons were determined for each Odorant as compared to the control (no odorant) as well as subgroupings based on age and hedonics (i.e., like/dislike of the odorant mixture).*

Finally, the Pilot Study demonstrates the role of body mass index (BMI) of the second person on the effect of the inhaled odorant compositions. See at paragraph [0048] and the discussion at paragraph [0052] (emphasis added).

[0048] Pilot Study. In a pilot study conducted prior to the test study, a lavender odorant, pumpkin pie odorant, and cinnamon odorant, were individually applied in three different sessions to a woman subject who had a *body mass index (BMI) of 23.0 as opposed to a BMI of 36.2 of the model in the test study*. Despite the hedonically positive nature of the three odorants (i.e., lavender, pumpkin pie, cinnamon), none of the three odorants provided a weight-reducing effect on the perception of a group of male observers. The men judged the model not to weigh any less in the presence of the three odorants that were tested.

...
[0052] *The results of the pilot study indicate that the effect of the odorant/odorant mixture can be less pronounced in cases in which the individual has a low body weight and is at a maximally attractive weight, such that the observer may or may not perceive the individual as weighing less, and/or relates a low body weight as being too thin and unattractive. Although Applicant does not intend to be bound by theory, it is believed that there is a body mass threshold at which the odorant/odorant mixture does not significantly alter the perception of body weight due to the body size of the individual.* In the pilot study, the model was not judged to weigh any less in the presence of any of the three odorants. The model's BMI was 23.0 as opposed to the BMI of 36.2 of the model in the test study. It is believed that the model in the pilot study was already at a maximal attractive weight, *and that the method of the invention is more effective to alter perception of the body weight of individuals whose BMI is greater than 25.0, the medically defined threshold for being overweight.* (National Heart, Lung, and Blood Institute, Body Mass Index Table: Obesity Guidelines (2001)).

Applicant has provided a sufficiently supporting disclosure, both through the descriptive discussion and experimental example showing guidance and what is well known to those of ordinary skill in the art, to teach one of skill in the art how to practice each of the elements of the methods as claimed without undue experimentation.

Based on Applicant's disclosure and the understanding in the art, it is submitted that the requirements under Section 112(1) have clearly been met in the present disclosure, and that an art worker in this area is fully enabled to practice Applicant's invention as broadly as it is claimed.

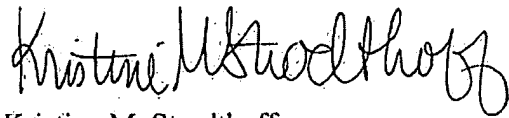
Accordingly, it is respectfully submitted that the claims fully comply with Section 112(1), and withdrawal of this rejection is respectfully requested.

Extension of Term.

The proceedings herein are for a patent application and the provisions of 37 CFR § 1.136 apply. Applicant believes that a two-month extension of term is required. Please charge the required fee (large entity) to Account No. 23-2053. If an additional extension is required, please consider this a petition therefor, and charge the required fee to Account No. 23-2053.

It is respectfully submitted that the claims are in condition for allowance and notification to that effect is earnestly solicited.

Respectfully submitted,



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